



PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	10/530,253-Conf. #5501
				Filing Date	April 4, 2005
				First Named Inventor	Maria Cristina Cassetti
				Art Unit	1648
				Examiner Name	A. R. Salimi
Sheet	1	of	4	Attorney Docket Number	00630/100M137-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A)	1.	US-6,365,160	04-02-2002	Webb et al.	
	2.	US-6,306,397	10-23-2001	Edwards et al.	
	3.	US-5,719,054	02-17-1998	Bourns et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.


NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
A)	1.	VON KNEBEL DOEBERITZ, M., et al., Inhibition of tumorigenicity of cervical cancer cells in nude mice by HPV E6-E7 anti-sense RNA, (1992) Int J Cancer 51, 831-4.		
	2.	CROOK, T., et al., Continued expression of HPV-16 E7 protein is required for maintenance of the transformed phenotype of cells co-transformed by HPV-16 plus EJ-ras, (1989) Embo J 8, 513-9.		
	3.	HE, Y., et al., Growth Inhibition of Human Papillomavirus 16 DNA-positive Mouse Tumor by Antisense RNA Transcribed from U6 Promoter, (1997) Cancer Res 57, 3993-9.		
	4.	SMOTKIN, D., et al., Transcription of human papillomavirus type 16 early genes in a cervical cancer and a cancer-derived cell line and identification of the E7 protein, (1986) Proc Natl Acad Sci U S A 83, 4680-4.		
	5.	DURST, M., et al., Human Papillomavirus Type 16 (HPV 16) Gene Expression and DNA Replication in Cervical Neoplasia: Analysis by in Situ Hybridization, (1992) Virology 189, 132-40.		
	6.	DYSON, N., et al., The Human Papilloma Virus-16 E7 Oncoprotein Is Able to Bind to the Retinoblastoma Gene Product, (1989) Science 243, 934-7.		
	7.	COBRINIK, D., et al., The Retinoblastoma protein and the regulation of cell cycling, (1992) Trends Biochem Sci 17, 312-5.		
	8.	SCHEFFNER, M., et al., The E6 Oncoprotein Encoded by Human Papillomavirus Types 16 and 18 Promotes the Degradation of p53, (1990) Cell 63, 1129-36.		
	9.	NAKAGAWA, M., et al., Cytotoxic T Lymphocyte Responses to E6 and E7 Proteins of Human Papillomavirus Type 16: Relationship to Cervical Intraepithelial Neoplasia, (1997) J Infect Dis 175, 927-31.		
	10.	KADISH, A. S., et al., Lymphoproliferative Responses to Human Papillomavirus (HPV) Type 16 Proteins E6 and E7: Outcome of HPV infection and Associated Neoplasia, (1997) J Natl Cancer Inst 89, 1285-93.		

Examiner Signature		Date Considered	5/29/06
--------------------	--	-----------------	---------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete If Known			
		Application Number	10/530,253-Conf. #5501		
		Filing Date	April 4, 2005		
		First Named Inventor	Maria Cristina Cassetti		
		Art Unit	1648		
		Examiner Name	A. R. Salimi		
Sheet	2	of	4	Attorney Docket Number	00630/100M137-US2

11.	FELTKAMP, M. C., et al., Cytotoxic T lymphocytes raised against a subdominant epitope offered as a synthetic peptide eradicate human papillomavirus type 16-induced tumors, (1995) Eur J Immunol 25, 2638-42.
12.	LIN, K. Y., et al., Treatment of Established Tumors with a Novel Vaccine That Enhances Major Histocompatibility Class II Presentation of Tumor Antigen, (1996) Cancer Res 56, 21-6.
13.	HORTON, R. M., et al., Engineering hybrid genes without the use of restriction enzymes: gene splicing by overlap extension, (1989) Gene 77, 61-8.
14.	PUSHKO, P., et al., Replicon-Helper Systems from Attenuated Venezuelan Equine Encephalitis Virus: Expression of Heterologous Genes in Vitro and Immunization against Heterologous Pathogens In Vivo, (1997) Virology 239, 389-401.
15.	DALAL, S., et al., Mutational Analysis of Human Papillomavirus Type 16 E6 Demonstrates that p53 Degradation Is Necessary for Immortalization of Mammary Epithelial Cells, (1996) J Virol 70, 683-8.
16.	SHI, W., et al., Human Papillomavirus Type 16 E7 DNA Vaccine: Mutation in the Open Reading Frame of E7 Enhances Specific Cytotoxic T-Lymphocyte Induction and Antitumor Activity, (1999) J Virol 73, 7877-81.
17.	GAO, Q., et al., Human Papillomavirus Type 16 E6-Induced Degradation of E6TP1 Correlates with Its Ability to Immortalize Human Mammary Epithelial Cells, (2001) J Virol 75, 4459-66.
18.	EDMONDS, C., et al., A Point Mutational Analysis of Human Papillomavirus Type 16 E7 Protein, (1989) J Virol 63, 2650-6.
19.	RESSING, M. E., et al., Human CTL Epitopes Encoded by Human Papillomavirus Type 16 E6 and E7 Identified Through In Vivo and In Vitro Immunogenicity Studies of HLA-A*0201-Binding Peptides, (1995) J Immunol 154, 5934-43.
20.	RESSING, M. E., et al., Occasional Memory Cytotoxic T-Cell Responses of Patients with Human Papillomavirus Type 16-positive Cervical Lesions against a Human Leukocyte Antigen-A*0201-restricted E7-encoded Epitope, (1996) Cancer Res 56, 582-8.
21.	EVANS, E. M., et al., Infiltration of Cervical Cancer Tissue with Human Papillomavirus-specific Cytotoxic T-Lymphocytes, (1997) Cancer Res 57, 2943-50.
22.	RAMMENSEE, H. G., et al., Peptides Naturally Presented by MHC Class I Molecules, (1993) Annu Rev Immunol 11, 213-44.
23.	VELDERS, M. P., et al., Eradication of Established Tumors by Vaccination with Venezuelan Equine Encephalitis Virus Replicon Particles Delivering Human Papillomavirus 16 E7 RNA, (2001) Cancer Res 61, 7861-7.
24.	BOURSNELL, M.E.G, et al., Construction and characterization of a recombinant vaccinia virus expressing human papillomavirus proteins for immunotherapy of cervical cancer, (1996) Vaccine 14, 1485-1494.
25.	BORYSIEWICZ, L.K., et al., A recombinant vaccinia virus encoding human papillomavirus types 16 and 18, E6 and E7 proteins as immunotherapy for cervical cancer, (1996) The Lancet 347, 1523-27.
26.	GAO, Q., et al., The E6 Oncoproteins of High-Risk Papillomaviruses Bind to a Novel Putative GAP Protein, E6TP1, and Target It for Degradation, (1999) Mol. and Cell. Biol. 19, 733-744
27.	DE JONG, A., et al., Enhancement of human papillomavirus (HPV) type 16 E6 and E7-specific T-cell immunity in healthy volunteers through vaccination with TA-CIN, an HPV16 L2E7E6 fusion protein vaccine, (2002) Vaccine 20, 3456-3464
28.	DAEMEN, T., et al., Immunization strategy against cervical cancer involving an alphavirus vector expressing high levels of a stable fusion protein of human papillomavirus 16 E6 and E7, (2002) Gene Therapy 9, 85-94
29.	Fields Virology (2001) Fourth Edition, Ch. 65 and 66, pps. 2197-2264 Knipe & Howley Eds., Lippincott Williams and Wilkins

Examiner Signature		Date Considered	5/24/06
--------------------	---	-----------------	---------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/530,253-Conf. #5501		
		Filing Date	April 4, 2005		
		First Named Inventor	Maria Cristina Cassetti		
		Art Unit	1648		
		Examiner Name	A. R. Salimi		
Sheet	3	of	4	Attorney Docket Number	00630/100M137-US2

30.	EIBEN GL et al., Establishment of an HLA-A*0201 Human Papillomavirus Type 16 Tumor Model to Determine the Efficacy of Vaccination Strategies in HLA-A0201 Transgenic Mice, Cancer Research, Oct. 15, 2002 Vol. 62, No. 20 pg 5792-5799
31.	ENGELHARD, V. H., et al., Influenza A-Specific, HLA-A2.1-Restricted Cytotoxic T Lymphocytes From HLA-A2.1 Transgenic Mice Recognize Fragments of the M1 Protein, (1991) J Immunol 146, 1226-1232
32.	SHIRAI et al., CTL Responses of HLA-A2.1-Transgenic Mice Specific for Hepatitis C Viral Peptides Predict Epitopes for CTL of Humans Carrying HLA-A2.1, (1995) J Immunol 154, 2733-2742
33.	ZUR HAUSEN, H., Papillomaviruses and Cancer: From Basic Studies to Clinical Application. Nat. Rev. Cancer, 2:342-350, 2002.
34.	WALBOOMERS, J. M., et al., Human Papillomavirus is a Necessary Cause of Invasive Cervical Cancer Worldwide. J. Pathol., 189:12-19, 1999.
35.	MUNGER, K., et al., Biological Activities and Molecular Targets of the Human Papillomavirus E7 Oncoprotein. Oncogene, 20:7888-7898, 2001.
36.	WALLIN, K. L., et al., Type-Specific Persistence of Human Papillomavirus DNA Before the Development of Invasive Cervical Cancer. N. Eng. J. Med., 341:1633-1638, 1999.
37.	MANTOVANNI, F., et al., The Human Papillomavirus E6 Protein and its Contribution to Malignant Progression. Oncogene, 20:7874-7887, 2001.
38.	EIBEN, G. L., et al., The Cell-Mediated Immune Response to Human Papillomavirus-Induced Cervical Cancer: Implications for Immunotherapy. Adv. Can. Res., 86:113-148, 2002.
39.	RAYNER, J. O., et al., Alphavirus Vectors and Vaccination. Rev. Med. Virol., 12:279-296, 2002.
40.	GRIFFIN, D. E., et al., Regulators of Apoptosis on the Road to Persistent Alphavirus Infection. Annu. Rev. Microbiol., 51:565-592, 1997.
41.	FELTKAMP, M. C. W., et al., Vaccination with Cytotoxic T Lymphocyte Epitope-Containing Peptide Protects Against a Tumor Induced by Human Papillomavirus Type 16-Transformed Cells. Eur. J. Immun. 23:2242-2249, 1993.
42.	GRIEDER, F. B., et al., Specific Restrictions in the Progression of Venezuelan Equine Encephalitis Virus-Induced Disease Resulting from Single Amino Acid Changes in the Glycoproteins. Virology 206:994-1006, 1995.
43.	KAST, W. M., Brandt, et al., Role of HLA-A Motifs Identification of Potential CTL Epitopes in Human Papillomavirus Type 16 E6 and E7 Proteins. J. Immunol., 152:3904-3912, 1994.
44.	HO, G. Y. F., et al., Natural History of Cervicovaginal Papillomavirus Infection in Young Women. N. Eng. J. Med., 338:423-428, 1998.
45.	DAEMEN, T., et al., Eradication of Established Hpv16-Transformed Tumours after Immunisation with Recombinant Semliki Forest Virus Expressing a Fusion Protein of E6 and E7. Vaccine, 21:1082-1088, 2003.
46.	CHENG, W. F., et al., Cancer Immunotherapy Using Sindbis Virus Replicon Particles Encoding a Vp22-Antigen Fusion. Hum. Gene Ther., 13:553-568, 2002.
47.	MACDONALD, G. H., et al., Role of Dendritic Cells Targeting Venezuelan Equine Encephalitis Virus Pathogenesis. J. Virol., 74:914-922, 2000.
48.	GARDNER, J. P., Frolov, et al., Infection of Human Dendritic Cells by a Sindbis Virus Replicon Vector is Determined by a Single Amino Acid Substitution in the E2 Glycoprotein. J. Virol. 74:11849-11857, 2000.
49.	NAKAGAWA, M., Stites, et al., Persistence of Human Papillomavirus Type 16 Infection is Associated with Lack of Cytotoxic T Lymphocyte Response to the E6 Antigens. J. Inf. Dis., 182:595-598, 2000.
50.	WELTERS, M. J. P., et al., Frequent Display of Human Papillomavirus Type 16 E6-Specific Memory T-Helper Cells in the Healthy Population as Witness of Previous Viral Encounter. Can. Res., 63:636-641, 2003.

Examiner Signature		Date Considered	5/29/06
--------------------	---	-----------------	---------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/530,253-Conf. #5501
				Filing Date	April 4, 2005
				First Named Inventor	Maria Cristina Cassetti
				Art Unit	1648
				Examiner Name	A. R. Salimi
Sheet	4	of	4	Attorney Docket Number	00630/100M137-US2

51.	Harrison's Principles of Internal Medicine (2001) Fifteenth Edition, p. 1119, Braunwald et al. Eds., McGraw-Hill	
52.	JEWERS et al., Regions of Human Papillomavirus Type 16 E7 Oncoprotein Required of Immortalization of Human Keratinocytes, (1992) J. Virol 66, P. 1329-1335	
53.	DAEMEN et al., Genetic immunization against cervical carcinoma: induction of cytotoxic T lymphocyte activity with a recombinant alphavirus vector expressing human papillomavirus type 16 E6 and E7, (2000) Gene Therapy, 7, P. 1859-1866	
54.	LONGUET et al., Two Novel Genital Human Papillomavirus (HPV) Types, HPV68 and HPV70, Related to the Potentially Oncogenic HPV39, (1996) Journal of Clinical Microbiology, p. 738-744	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	5/29/06
--------------------	---	-----------------	---------

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Maria C. Cassetti
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	00630/100M137-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AC	AA	US-6,004,557-A	12-21-1999	Edwards et al.	


FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
AC	CA	Mantovani et al., "The Human Papillomavirus E6 Protein and its Contribution to Malignant Progression," <i>Oncogene</i> , 2001, vol. 20, pages 7874-7887.	
AC	CB	Munger et al., "Biological Activities and Molecular Targets of the Human Papillomavirus E7 Oncoprotein," <i>Oncogene</i> , 2001, vol. 20, pages 7888-7898.	
AC	CC	Velders et al., "Eradication of Established Tumors by Vaccination with Venezuelan Equine Encephalitis Virus Replicon Particles Delivering Human Papillomavirus 16 E7 RNA," <i>Cancer Research</i> , 01 November 2001, pages 7861-7867.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	5/24/06
--------------------	---	-----------------	---------